INTERNATIONAL STANDARD

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AMENDMENT 1
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Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —

Part 1:
General requirements

AMENDMENT 1

Dispositifs médicaux — Symboles à utiliser avec les étiquettes, l'étiquetage et les informations à fournir relatifs aux dispositifs médicaux —

Partie 1: Exigences générales

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Amendment 1 to ISO 15223-1:2007 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

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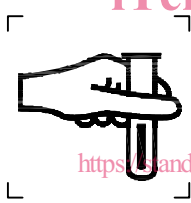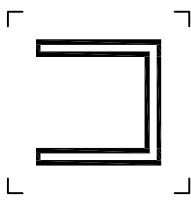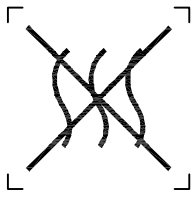iTeh STANDARD PREVIEW
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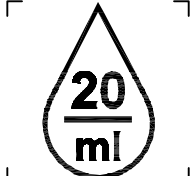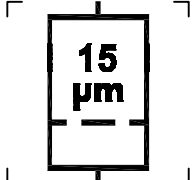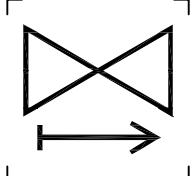
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Page 8, Table 1

Add the following symbols to Table 1.

No.	Symbol	Title	ISO 7000 or IEC 60417 registration number
5.32		Sampling site	ISO 7000-2715
5.33		Fluid path	ISO 7000-2722
5.34		Non-pyrogenic	ISO 7000-2724
5.35	LATEX	Contains or presence of natural rubber latex NOTE This symbol should be used only when natural rubber latex is a material of construction within the device or the packaging of a device. It is intended to warn those people who may have allergic reactions to certain proteins in natural rubber latex. This symbol should not be used for devices containing "synthetic" rubber.	Derived from ISO 7000-2725

No.	Symbol	Title	ISO 7000 or IEC 60417 registration number
5.36		Drops per millilitre NOTE On medical devices: to indicate the number of drops per millilitre. The number of drops per millilitre is specified; "20" is shown as an example and should be replaced by the correct number of drops per millilitre.	ISO 7000-2726
5.37		Liquid filter with pore size NOTE On medical devices: to indicate that the infusion or transfusion system contains a liquid filter in various sizes. The nominal pore size of the filter is specified; "15" is shown as an example and should be replaced by the correct pore size.	ISO 7000-2727
5.38		One-way valve	ISO 7000-2728

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